

APR 24 2003

K030984

Special 510(k) Premarket Notification
ILT Safe Cross[®] Support Catheter

510(k) Summary of Safety and Effectiveness

SUBMITTER INFORMATION

- A. Company Name: IntraLuminal Therapeutics, Inc.
- B. Company Address: 6354 Corte Del Abeto -- Suite A
Carlsbad, CA 92009
- C. Company Phone: (760) 918-1820
- D. Company Facsimile: (760) 918-1823
- E. Contact Person: Pamela Misajon
Vice President of Regulatory Affairs and Quality Assurance

DEVICE IDENTIFICATION

- A. Device Trade Name: Safe Cross[®] Support Catheter
- B. Catalog Number: C114AN1 –Safe Cross[®] .014" Angled Support Catheter
C114SN1 –Safe Cross[®] .014" Straight Support Catheter
C118AN1 –Safe Cross[®] .018" Angled Support Catheter
C118SN1 – Safe Cross[®] .018" Straight Support Catheter
- C. Device Common Name: Percutaneous Catheter
- D. Classification Name: Percutaneous Catheter
- E. Device Class: Class II (per 21 CFR 870.1250)

IDENTIFICATION OF MODIFIED DEVICE

The Safe Cross[®] Support Catheter is a similar in design, materials, mode of operation and intended use to the IntraLuminal Therapeutics, Inc. 0.014" Support Catheter cleared under 510(k) K012169. The device modification includes the devices to be coated with a hydrophilic coating and a new .018" Support Catheter Model. The new .018" Support Catheter is a single lumen intravascular catheter with same intended use. But will accommodate a .018" guide wire.

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DEVICE DESCRIPTION

The Safe Cross® Support Catheter is a single-lumen intravascular catheter intended for percutaneous use. It is designed to use in conjunction with a .014" and .018" guide wire to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guide wires may be exchanged within the catheter. The Safe Cross® Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

The effective length of the Support Catheter is a nominal 135 cm. The nominal maximum outside diameter is 2.8 French (0.037"). The distal region incorporates a radiopaque material to aid in visualization under fluoroscopy. The inside diameter of the Support Catheter shaft will accommodate a commercially available .014" and .018" guide wire.

The Safe Cross® Support Catheter is packaged in a Tyvek® covered tray and heat-sealed to form a sterile barrier. The packaged catheter is sterilized by ethylene oxide gas. The Safe Cross® Coated Support Catheter is provided "STERILE" and "Non-pyrogenic", and is intended for single use only.

INTENDED USE

The Safe Cross® Support Catheter is indicated to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guidewire for another can occur. The Safe Cross® Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TECHNOLOGICAL CHARACTERISTICS

The Safe Cross® Support Catheter is similar in basic materials, design, construction and mechanical performance to the previously cleared .014" Catheter. The device modification includes the devices to be coated with a Bio-coat Hydak® hydrophilic coating and an additional .018" Support Catheter Model.

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing and *in vitro* bench studies were conducted to evaluate the biological and performance characteristics of the Support Catheter. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the modifications to the Safe Cross® Support Catheter are substantially equivalent to the predicate device and are capable of safely and accurately performing the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 24 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

IntraLuminal Therapeutics, Inc.
Ms. Pamela Misajon
Vice President of Regulatory Affairs and Quality Assurance
6354 Corte Del Abeto - Suite A
Carlsbad, CA 92009

Re: K030984
Trade/Device Name: Safe Cross® Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 15, 2003
Received: April 16, 2003

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

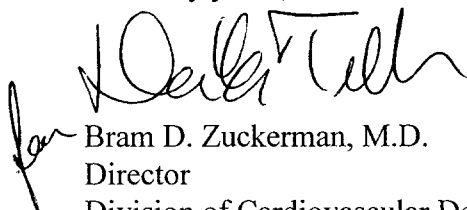
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive, flowing style. To the left of the signature, there is a small, handwritten word that appears to be "for".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.6 INDICATIONS FOR USE FORM

INDICATIONS FOR USE

510(k) Number:

K030984

Device Name:

Safe Cross[®] Support Catheter

Indications For Use:

The Safe Cross[®] Support Catheter is indicated to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guidewire for another can occur. The Safe Cross[®] Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030984